

## Using Mifeprex - Medication Guide

<http://www.earlyoptionpill.com>

**R**ead this information carefully before taking Mifeprex and misoprostol. It will help you understand how the treatment works. This Medication Guide does not take the place of talking with your health care provider (provider).

### **What is the most important information I should know about Mifeprex?**

**Mifeprex is used to end an early pregnancy.** It is not approved for ending later pregnancies. Early pregnancy means it is 49 days (seven weeks) or less since your last menstrual period began. By using Mifeprex, you probably will not need a surgical procedure to end your pregnancy.

**When you use Mifeprex, you also need to take another medicine called misoprostol.** You take misoprostol 2 days after you take Mifeprex.

**You need to sign a statement (PATIENT AGREEMENT).** Before you get Mifeprex, you will need to read and understand the information in this Medication Guide. Then you will need to sign a statement that you have decided to end your pregnancy.

**You must visit your provider on Day 1, Day 3, and about Day 14.** See the section called "How should I take Mifeprex?" for information about what happens at each visit. If you do not follow all the steps in "How should I take Mifeprex?" you will not know if your pregnancy has ended.

**What to do if you are still pregnant after Mifeprex or Mifeprex with misoprostol treatment.** If you are still pregnant, your provider will talk with you about the other choices you have, including a surgical procedure to end your pregnancy. There is a chance that there may be birth defects if the pregnancy is not ended.

**Symptoms to expect.** This treatment causes cramping and bleeding. Usually, these symptoms mean that the treatment is working. But sometimes you can get cramping and bleeding and still be pregnant. This is why you must return to your provider on Day 3 and about Day 14.

If you are not already bleeding after taking Mifeprex, you probably will begin to bleed once you take misoprostol. This is a medicine you take on Day 3. Bleeding or spotting can be expected for an average of nine to 16 days and may last for up to 30 days. Your bleeding may be similar to, or greater than, a normal heavy period. You may see blood clots and tissue that come from your uterus. This is an expected part of ending the pregnancy.

**Heavy bleeding and the need for surgery.** In about 1 out of 100 women, bleeding can be so heavy that it requires a surgical procedure (curettage) to stop it. This is why you must talk with your provider about what to do if you need emergency care to stop heavy and possibly dangerous bleeding.

**Before you take Mifeprex.** Your provider will give you a telephone number to call if you have any questions, concerns, or problems. Your provider will also give you the name and phone number of who will handle emergencies.

**Talk with your provider.** You and your provider should discuss the benefits and risks for you of using Mifeprex.

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## **What is Mifeprex?**

Mifeprex blocks a hormone needed for your pregnancy to continue. When used together with another medicine called misoprostol, Mifeprex ends your pregnancy. About five to eight out of 100 women taking Mifeprex will need a surgical procedure to end the pregnancy or to stop too much bleeding.

## **Who should not take Mifeprex?**

Some women should not take Mifeprex. Do not take it if:

- It has been more than 49 days (seven weeks) since your last menstrual period began.
- You have an IUD. It must be taken out before you take Mifeprex.
- Your provider has told you that you have a pregnancy outside the uterus (ectopic pregnancy).
- You have problems with your adrenal glands (chronic adrenal failure).
- You take a medicine to thin your blood.
- You have a bleeding problem.
- You take certain steroid medicines.
- You cannot return for the next two visits.
- You cannot easily get emergency medical help in the two weeks after you take Mifeprex.
- You are allergic to mifepristone, misoprostol, or medicines that contain misoprostol, such as Cytotec or Arthrotec.

Tell your provider about all your medical conditions to find out if you can take Mifeprex. Also, tell your provider if you smoke at least 10 cigarettes a day.

## **How should I take Mifeprex?**

### **• Day 1 at your provider's office:**

- Read this Medication Guide.
- Discuss the benefits and risks of using Mifeprex to end your pregnancy.
- If you decide Mifeprex is right for you, sign the PATIENT AGREEMENT.
- After getting a physical exam, swallow three tablets of Mifeprex.

### **• Day 3 at your provider's office:**

- Your provider will check to see if you are still pregnant.
- If you are still pregnant, take two misoprostol tablets.
- Misoprostol may cause cramps, nausea, diarrhea, and other symptoms. Your health care provider may send you home with medicines for these symptoms.
- About Day 14 at your provider's office:
  - This follow-up visit is very important. You must return to the provider about 2 weeks after you took Mifeprex to be sure you are well and that you are not pregnant.
  - Your provider will check whether your pregnancy has completely ended. If it has not ended, there is a chance that there may be birth defects. If you are still pregnant, your provider will talk with you about the other choices you have, including a surgical procedure to end your pregnancy.

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**What should I avoid while taking Mifeprex and misoprostol?**

You should not take certain other medicines, because they may interfere with the treatment. Ask your provider about what medicines you can take for pain. Do not take any other prescription or non-prescription medicines (including herbal medicines or supplements) at any time during the treatment period without first asking your provider about them.

If you are breastfeeding at the time you take Mifeprex and misoprostol, discuss with your provider if you should stop using your breast milk for a few days.

**What are the possible side effects of using Mifeprex?**

See the section "What is the most important information I should know about Mifeprex?" for symptoms to expect.

In some cases, bleeding can be very heavy. In a very few cases, this bleeding will need to be stopped by a surgical procedure. Contact your provider right away if you bleed enough to soak through two thick full-size sanitary pads per hour for two consecutive hours or if you are concerned about heavy bleeding.

Other side effects of the treatment include diarrhea, nausea, vomiting, headache, dizziness, back pain, and tiredness. These side effects lessen after Day 3 and are usually gone by Day 14. Your provider will tell you how to manage any pain or other side effects.

If you are worried about any side effects you have, talk with your provider about them. Your provider will give you a telephone number to call if you have any questions, concerns, or problems. Your provider's telephone number is \_\_\_\_\_.

**When should I begin birth control?**

You can become pregnant again right after your pregnancy ends. If you do not want to become pregnant again, start using birth control as soon as your pregnancy ends or before you start having sexual intercourse again.

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Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. For more information, ask your provider for the information about Mifeprex that is written for health care professionals. Ask your provider if you have any questions.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

*Source:* Danco Laboratories, New York City.